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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/983,474	06/30/1998	DAVID KLATZMANN	31649-134353	1470
7590	09/27/2005		EXAMINER	
VENABLE POST OFFICE BOX 34385 WASHINGTON, DC 20005-3917			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 09/27/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/983,474	KLATZMANN ET AL.
	Examiner	Art Unit
	Prema M. Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 June 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17, 20 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6 and 20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 7-17 and 22-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 18-19 have been canceled previously. Claims 1-4, 7-17, and 22-26 and new claims 27-31 (6/16/2005) are under consideration.

In response to the restriction requirement of 12/21/1998, Applicants elected the species "antigens and antigen fragments" (see response of 1/20/99. Therefore, claims 1-4, 7-17 and 22-31 drawn to the elected species are under consideration by the Examiner.

Claim 20 is a diagnostic test kit (class 435/subclass 810) encompassing using the claimed recombinant multimeric product (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995), in which a new, unobvious material is used in a known process). Ochiai determined that a process was free of the prior art if it employed a product, which was free of the prior art. However, only if the product claims are found allowable, the subject matter of the kit will be rejoined with the product claims, if the kit claims are of the same scope as the allowable product claims.

2. Receipt of applicant's arguments and amendments filed on 6/16/2005 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 6/16/2005:

- (i) the rejection of claims 1-17, 20, 22-26 under 35 USC 112, first paragraph, enablement.

4. Applicant's arguments filed on 6/16/2005 have been fully considered and were persuasive in part. The issues remaining and new issues are restated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*New claim rejections-35 USC § 112, second paragraph*

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6. Claims 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27, 28, 29, 30, 31, are vague and indefinite because they recite "... contained in SEQ ID NO:...." rather than the conventional "... of amino acid sequence set forth in SEQ ID NO:....". Appropriate correction is requested.

Claims 28-31 recite "ligand of the immune system" which is vague and indefinite because the metes and bounds of the term are unclear. Claim 4 recites "specific ligands of the immune system" while claims 28-31 recite "ligand of the immune system". It is suggested that to obviate this rejection, the claims be amended to recite the list of the ligands of the immune system without recitation of the term "specific".

***Claim rejections-35 USC § 112, first paragraph***

7. Claim 14 is rejected under 35 USC § 112, first paragraph for failing to comply with the deposit requirements.

This rejection is maintained for reasons of record set forth at pages 6-7 of the previous Office action (4/27/99).

Since Applicants have failed to comply with the deposit requirements, this rejection is maintained for reasons of record.

***Claim rejections-35 USC § 102(b)***

8. Claims 1-4, 7-17, 21-26, are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/11461.

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (3/16/2005).

Applicants argue that claims 1 and 12 have been amended. However, Applicants have failed to amend claims 1 and 12 to recite the specific SEQ ID NOS to obviate this rejection and therefore this rejection is being maintained for reasons of record.

The prior art reference on page 4, lines 12-17, clearly teaches that in addition to seven C4bp  $\alpha$  monomers, human C4bp contains a 45 kD  $\beta$  monomer. Furthermore, on page 31, lines 5-10, the reference clearly teaches how to make fusions. Therefore, contrary to Applicants arguments, the  $\beta$  monomer would be implicit in the recombinant multimeric protein because the  $\beta$  monomer was known at the time of the reference, as is also evident from Applicants disclosure (Hillarp et al. , page 1, lines 27-32). Therefore, the reference anticipates the claims.

### ***Conclusion***

Claims 27-31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
September 20, 2005